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(54) APPARATUS FOR TREATING TISSUE DAMAGE

VORRICHTUNG ZUM BEHANDELN VON GEWEBESCHÄDEN

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(56) References cited:

WO-A-90/11759	DE-C- 561 757
US-A- 3 026 874	US-A- 3 367 332
US-A- 3 874 387	US-A- 3 896 810
US-A- 3 954 105	US-A- 4 112 947
US-A- 4 224 945	US-A- 4 250 882
US-A- 4 382 441	US-A- 4 834 110

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EP 0 620 720 B1

**Description**Field of the Invention

5 This invention relates generally to wound healing, and more specifically is directed to apparatus for treating wounds that are unlikely to heal completely under conventional methods.

Background of the Invention

10 The treatment of open wounds that are too large to spontaneously close has been a troublesome area for many years. Wound closure requires that epithelial and subcutaneous tissue adjacent to the wound migrate toward and eventually close the wound. Some wounds are sufficiently large or infected that they are unable to close spontaneously. In such instances, a zone of stasis, an area in which localized swelling of tissues restricts the flow of blood to these tissues, forms near the surface of the wound. Without sufficient blood flow, the wound is unable to successfully fight bacterial infection and accordingly is unable to close spontaneously.

15 The most common technique for closure of open wounds has long been the use of sutures or staples. These mechanical closure methods provide tension on the skin tissue at the wound border that encourages epithelial tissues to migrate toward the wound and cover it. While suturing and stapling of wounds is widely practiced, it has a major drawback: the tensile force required to achieve closure with sutures or staples causes very high localized stresses at the suture insertion points, resulting in the rupture of the tissue at these points. Substantial rupture will eventually cause dehiscence in some wounds, which results in additional tissue loss. Moreover, some infected wounds harden and inflame to such a degree that closure by suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalizations with its attendant high costs, and major surgical procedures, such as grafts of surrounding tissue. Examples of such wounds include large, deep, open wounds, pressure sores resulting from prolonged pressure, ulcers resulting from chronic osteomyelitis, and partial thickness burns that subsequently develop into full thickness burns.

20 To date, there has been no consistently satisfactory method for treating such wounds. What is needed is a method of closing the wound without the localized stresses that accompany suturing while at the same time treating any infection present in the wound along with a simple apparatus to carry out the method. Such a method and apparatus would reduce hospitalization and increase the probability of wound closure.

30 WO-A-90/11795 relates to a fluidic connection system for wound drainage or fluid introduction. The device comprises a cover membrane which overlies a wound. The proximate end of a tube fluidically communicates with the wound through an opening in the cover membrane. The device can be operated to evacuate or introduce fluids in either an active or a passive manner. When operated in an active mode, the distal end of the tube is connected to a suction source for draining the wound or to a fluid source for introducing fluid into the wound.

Summary of the Invention

40 The invention provides an apparatus for facilitating the healing of a wound according to claim 1. A preferred embodiment of the invention comprises an open-cell polymer foam section configured to overlie a wound, and a flexible tube having an inlet end and an outlet end, said inlet end being inserted into said open cell polymer foam section. A flexible polymer sheet may overlie the foam section and tubing and be configured to be adhered to the skin surrounding the wound.

45 The invention will now be further described, by way of example, with reference to the accompanying drawings, in which:

Brief Description of the Drawings

50 Figure 1 shows a cross-sectional view of a negative pressure device comprising a open-cell polymer screen, a flexible hose connecting the foam section to a suction pump, and a flexible polymer sheet overlying the foam-hose assembly to provide the necessary seal; and

Figure 2 shows a cross-sectional view of a negative pressure device comprising a porous screen, an inflatable cuff attached to a semi-rigid cup, and a flexible hose extending from a suction pump to a point within the sealed volume of the cup-cuff assembly.

55

Detailed Description of the Invention

The present invention relates to an apparatus for treating tissue damage according to claim 1. Wound closure

requires that epithelial and subcutaneous tissue migrate from the wound border toward the wound. The use of negative pressure provides tension on this border tissue that causes accelerated tissue migration. It has been observed that the use of the apparatus also causes within the wound increased formation of granulation tissue, a matrix of collagen, fibronectin, and hyaluronic acid carrying macrophages, fibroblasts, and neovasculature that aids in healing.

5 Apparatus according to the invention is particularly suited for use on pressure sores. A pressure sore is a wound that develops due to constant compressive pressure on the skin surface and underlying tissue. Blood flow to the compressed tissue is restricted to the extent that the overlying tissue dies and subsequently allows the underlying tissue to become infected. The decrease of blood flow to the wound prevents a normal immune reaction to fight the infection, the presence of which prevents tissue migration from the wound border. Pressure sores often occur on bedridden patients  
10 who are unable to feel the sore or to move sufficiently to relieve the contact pressure. Such wounds can become very serious, requiring extensive and repeated skin grafts; some are even fatal. As described above, application of negative pressure to the sore permits migration of wound border tissue to occur and thus allows sores to heal without these more drastic procedures.

The invention can be practiced with the application of substantially continuous negative pressure, where the pressure is relieved only to change the dressing on the wound, or it can be practiced with the use of a cyclic application of  
15 pressure in alternate periods of application and non-application. The ratio of duration of application period to non-application period can be as low as 1:10 or as high as 10:1, but is most preferably 1:1. A preferred pattern is 5 minutes of pressure application followed by 5 minutes of relief.

The invention is practiced using a negative pressure ranging from 10.1 and 100.3 kPa (0.01 to 0.99 atmospheres)  
20 and more preferably practiced using a negative pressure ranging between 50.7 and 81.1 kPa (0.5 to 0.8 atmospheres). The time period for use of the method on a wound is preferably at least 12 hours, but can be, for example, 1 day, 2 days, 5 days, 7 days, 14 days, 30 days, or even longer. There is no upper limit beyond which use of the method is no longer beneficial; the method increases the rate of closure up to the time the wound actually closes.

Open wounds are almost always contaminated with harmful bacteria. Generally a bacterial density of  $10^5$  bacterial  
25 organisms per gram of tissue is regarded as infected. (It is generally accepted that at this level of infection, grafted tissue will not adhere to a wound). These bacteria must be killed, either through the wound host's natural immune response or through some external method, before a wound will close. We have observed that application of negative pressure to a wound will reduce the bacterial density of the wound; it is believed that this effect is due to either the bacteria's incompatibility with a negative pressure environment or the increased blood flow to the wound area, as blood  
30 brings with it cells and enzymes to destroy the bacteria.

The invention can be used to reduce bacterial density in a wound by at least half. More preferably, it can be used to reduce bacterial density by at least 1,000 fold. Most preferably, the method can be used to reduce bacterial density by at least 1,000,000 fold. The ranges of pressure magnitude and application duration are as described above, although  
35 Example 3 demonstrates dramatic reduction in wound contamination after a 4-day application of negative pressure. Pressure can be applied continuously or cyclically in the application/nonapplication ratios described above.

The present invention may also be used for treating a burn. A partial thickness burn, one which has a surface layer of dead tissue and an underlying zone of stasis, is often sufficiently infected that it will transform within 24-48 hours into a full thickness burn, one in which all epidermal structures are destroyed. As explained above, the application of a negative pressure to the wound prevents the infection from becoming sufficiently severe to cause destruction of the  
40 underlying epidermal structures. As above, the magnitude, pattern, and duration of pressure application can vary with the individual wound.

The present invention also serves to enhance the attachment of living tissue to a wound. Attachment of living tissue to a wound is a common procedure that can take many forms. For example, one common technique is the use of a "flap", a technique in which skin tissue from an area adjacent to the wound is detached on three sides but remains  
45 attached on the fourth, then is moved onto the wound. Another frequently used technique is an open skin graft in which skin is fully detached from another skin surface and grafted onto the wound. The application of negative pressure to the wound-graft complex reduces bacterial density in the complex and improves blood flow to the wound, thereby improving the attachment of the grafted tissue.

The acceptable ranges of time, magnitude, and application/non-application ratio are as described above. Each of  
50 these variables is affected by the size and type of wound.

Apparatus according to the present invention for facilitating the healing of wounds comprises vacuum means such as a pump for creating a negative pressure on the area of skin surrounding the wound, sealing means such as an adhesive sheet operatively associated with the vacuum means for maintaining negative pressure on the wound by contacting the skin surrounding the wound, and screen means such as an open-cell foam section located within the sealing means  
55 for preventing the overgrowth of tissue in the wound area.

The screen means is placed over substantially the expanse of the wound to prevent its overgrowth. The size and configuration of the screen can be adjusted to fit the individual wound. It can be formed from a variety of porous semi-rigid materials. The material must be sufficiently porous to allow oxygen to reach the wound, and sufficiently rigid to pre-

vent wound overgrowth. Most preferred is the use of an open-cell polymer foam, which permits direct connection of the screen means to the vacuum means through a flexible hose inserted into the foam. Such foam can vary in thickness and rigidity, although it is preferred that a spongy material be used for the patient's comfort if the patient must lay upon the device during its operation. It can also be perforated to reduce its weight. Another embodiment comprises a section of honeycombed polyethylene sheet cut to the shape of the wound.

Possible sealing means include a flexible sealing rim contacting the skin surrounding the wound, a flexible polymer sheet overlying the screen means and the vacuum means and attached to the skin through an adhesive applied to the sheet surface facing the skin, and an inflatable sealing cuff that conforms to the skin when inflated and that is held in place by the suction of the vacuum means. If an adhesive sheet is used, it must have sufficient adhesion to remain in contact with the skin and form a seal under the negative pressure. Additionally, it must be sufficiently flexible to overlay the screen means and still conform to the skin around the wound. The sealing means also can include a semi-rigid cup that protects the wound from external contact. For example, a suitable cup-cuff assembly is provided by an adult CPR mask with an inflatable sleeve.

Suitable vacuum means includes any suction pump capable of providing at least 689.5 Pa (0.1 psi) suction to the wound, and preferably up to 20.7 kPa (3 psi) suction, and most preferably up to 96.5 kPa (14 psi) suction, and a flexible hose that leads from the pump to a point within the pressurized volume created by the sealing means. The pump can be any ordinary suction pump suitable for medical purposes that is capable of providing the necessary suction. The dimension of the tubing are limited only by the pump's ability to provide the suction level needed for operation. A 6.4 mm (1/4 inch) diameter tube has proven suitable. The vacuum means may operate substantially continuously, or may operate cyclically with alternate periods of application and nonapplication of pressure to the wound.

A preferred embodiment of the invention, shown in Figure 1, comprises a substantially flat section of open cell polyester foam section 10 (Fischer Scientific, Pittsburgh, PA 15219) sufficiently large to cover the wound and thus prevent wound overgrowth, a flexible hollow tube 11 (Fischer Scientific) inserted into the open cell foam section 10 and joined thereto with an adhesive and extending to attach at its opposite end to a Cast Vacuum pump (Fischer Scientific), and an Ioban adhesive sheet 12 (Minnesota Mining and Manufacturing, St. Paul, MN. 55144) overlying the foam section 10 and tubing 11 and adhered to the skin surrounding the wound, thus forming a seal that allows creation of a vacuum when the suction pump operates. Such an apparatus would most preferably be packaged in a sterile condition to ameliorate the need for sterilization of the apparatus prior to use (note that the adhesive sheet 12 could be packaged separately from the foam-tube assembly). A particular advantage of this configuration is its use with pressure sores: the device can be placed in the depths of the wound and the patient can lie upon it without either affecting the utility of the device or further damaging the wound. This becomes critical if the patient cannot be moved from this posture for other medical reasons.

The present invention is explained further in the following examples. These examples are provided for illustrative purposes only and are not to be taken as limiting.

#### EXAMPLE 1

##### Rate of Wound Healing under Negative Pressure

This example demonstrates the use of negative pressure to increase the rate of healing of full thickness defects by increasing vascularity and the amount of granulation tissue present.

Fifteen-kilogram pigs were obtained and conditioned for 1 week prior to use. The backs of the pigs were shaved and scrubbed for surgery. Two full thickness circular defects were created on the midline of the animals, 2.5 cm in diameter and 1 cm thick. Alginate impressions were taken of each defect to determine its volume. Cefazolin (Kefzol) (500 mg) was administered intramuscularly (antibiotic). The suction devices used, shown in Figure 2, comprised an adult CPR mask 20 (Doug Brown and Associates, Huntington Beach, CA 92648) comprising a semi-rigid cup 21 and inflatable cuff 22 in contact with the skin, an open cell polyester screen 24 overlying the wound, and a flexible 6.4 mm (1/4 inch) diameter hose 23 (Fischer Scientific) connected by a Nalgene tubing connector to a vacuum pump (Fischer Scientific) and extending through a sealed hole in the cup. Each device was configured such that the suction hose ran from the cup on the animal up through a pulley suspended over the center of the pen and down to a vacuum trap bottle to collect any liquid exudate, then down to the vacuum pump. A suction device was attached over each defect, and suction of 13.8 to 41.4 kPa (2-6 psi) was applied to one of the devices. The devices were removed only so that impressions could be made of each defect. This procedure was continued until the volume of both defects was zero.

Table 1 shows data expressed as the amount of granulation tissue formed per day and as the percent difference in rate of granulation tissue formation. The data shows that in all cases the use of negative pressure increased the rate of wound closure and the formation of granulation tissue at a statistically significant rate.

## EXAMPLE 2

Rate of Burn Healing under Negative Pressure

5 This example was designed to demonstrate the use of continuous closed suction for the treatment of deep, partial thickness thermal burns (second degree burns).

The backs of 15 kg pigs were shaved and scrubbed for surgery. A 38 mm (1.5 inch) diameter brass rod was heated to 190°C in an oil bath. The rod was pressed onto the pig's skin for 15 seconds following a well-known technique of relating depth of burn to time and temperature. Three burns were treated over the spine of each pig, separated by 5 cm intervals. Suction apparatus cups of the configuration described above were placed over two of the burns, with silver sulphadiazine (Silvadine) cream, the standard antibiotic cream applied to human burns prior to excision of burned tissue, applied to the third. Cefazolin (Kefzol) (500 mg) was administered intramuscularly (antibiotic). Suction of 13.8 to 41.4 kPa (2-6 psi) was applied to one of the cups. A small (2 mm) punch biopsy was taken of the wounded area and examined histologically for depth of burn.

Table 1

Rate of granulation tissue formation for control and reduced pressure treated full thickness defects in pigs.			
Animal	Granulated Treatment	Tissue/Day (cc)	% Increase*
1	Suction	0.48	26.3
	Control	0.38	
2	Suction	1.16	28.9
	Control	0.90	
3	Suction	0.58	75.8
	Control	0.33	
4	Suction	0.71	65.1
	Control	0.43	
5	Suction	0.71	65.1
	Control	0.43	

\* (Suction-Control)/Control

Table 2

Rate of reduction in bacterial density for control and reduce and pressure treated pigs (n=5).								
treatment	Log Organisms Per Gram Tissue							
	Day 0		Day 1	Day 2	Day 3	Day 4	Day 5	Day 7
control	Mean	8.44	8.04	8.17	7.13	7.13	8.82	7.08
	SD	±.38	±.13	±.98	±.15	±.24	±1.12	±.52
vacuum	Mean	7.69	7.36	7.37	6.79	6.43	3.98	4.32
	SD	±.83	±.84	±1.40	±.55	±.45	±3.46	±3.74

Biopsies were analyzed by a dermatopathologist who was not told the nature of the study. It was concluded that the suctioned tissue specimens were healthier and healing more quickly than non-suctioned specimens.

## EXAMPLE 3

Reduction of Bacterial Density under Negative Pressure

5 This example illustrates the effects of continuous closed suction on the bacterial density of infected tissue. Fifteen-kilogram pigs were shaved and prepared for surgery. Two 2.5 cm diameter defects were created on the dorsum of each pig using sterile technique, with a 7.5 cm interval retained between the edges of the defects. Hemostasis was obtained by electrocautery. One ml of culture broth containing  $10^8$  Staph. aureus organisms was injected just beneath the surface tissue in the center of each wound. Suction cups of the configuration described above were placed  
10 over each defect, and a T-shirt was placed over the animal. Suction of 13.8 to 41.4 kPa (2-6 psi) was applied 24 hours after surgery to only one of the defects, allowing each animal to act as its own control. No antibiotics were given during the course of the study.

Each day, a small (3 mm biopsy punch) piece of granulation tissue was removed from the center of each defect. The number of organisms present in the tissue was determined by weighing the tissue, homogenizing the tissue, serially diluting the supernatant, and plating the diluted supernatant on blood agar plates. Samples of the original broth  
15 were treated in an identical manner to determine effects of mechanical manipulations on bacteria viability. The procedure was performed until the wounds were healed.

Table 2 compares the bacterial density of treated wounds and control wounds over time. The data is expressed as the mean log of the number of viable organisms per gram of tissue as a function of time. Clearly, the application of negative pressure increases the rate at which bacteria are destroyed. Using  $10^5$  organisms per gram of tissue as a baseline  
20 for infection, the data show that on average a suctioned wound was disinfected after 4 days of treatment, while the average non-treated wound was still infected after 7 days.

## EXAMPLE 4

25

Treatment of Pressure Sore With Negative Pressure

Mr. L.J. is a 45-year-old diabetic male who has been a paraplegic as the result of a gunshot wound for 12 years. He has a history of recurrent right ischeal fossa pressure sore and right trochanteric pressure ulcer. L.J. was admitted to  
30 the hospital for treatment and closure of the pressure sores. A flap was placed onto the wound and secured with sutures and staples.

The incisions of the flap dehiscd, resulting in a large, open wound. The tissues of the flap were very edematous and indurated. Nine days after the flap was detached, a negative pressure device was placed over the wound. The device comprised an open-cell polyester foam section (Fischer Scientific) approximately 12.7 mm (1/2 inch) in thickness  
35 attached to a suction pump by a flexible hose (Fischer Scientific) and covered and sealed by loban polymer sheet (Minnesota Mining and Manufacturing, St. Paul, MN 55144). A continuous vacuum of 34.5 kPa (5 psi) was applied to the wound. The design of the device allowed the patient to lay comfortably on the device during operation.

The depth of the wound decreased dramatically. The devices were changed and the wound examined on a three times per week basis. Reduced pressure treatment was continued for 6 weeks, at which time the wound was healed.  
40

## EXAMPLE 5

Treatment of Pressure Sore With Negative Pressure

45 Mr. W.E. is a 51-year-old male who had both legs amputated at the hip approximately 20 years ago. He was afflicted with a large pressure sore in the buttocks region. The pressure sore had been present 7 months and measured 200 mm (8 inches) laterally and 76 mm (3 inches) in its greatest width. An open cell foam reduced pressure device as described in Example 4 was placed over the wound and a negative pressure of 34.5 kPa (5 psi) was applied cyclically in alternate periods of 5 minutes on, 5 minutes off. The open cell foam device was used as the patient was lying on the  
50 device. The device was changed on a three times per week schedule.

After 5 weeks of treatment, the wound measured 76mm (3 inches) laterally and 38 mm (1.5 inches) at its greatest width. At that point the wound was essentially healthy granulation tissue that accepted a cultured keratinocyte allograft and healed completely.

55



## EXAMPLE 6

Treatment of Wound Dehiscence With Negative Pressure

5 Mr. C.L. is a 50-year-old male who had undergone a colostomy revision through a midline laparotomy. He was readmitted to the hospital for wound dehiscence and evisceration following forceful coughing. The abdominal wall was closed with Prolene mesh coverage. Six weeks after placement of the Prolene mesh, the wound was still open and measured 28 cm by 23 cm with sparse granulation tissue growth through the Prolene mesh. A large reduced pressure cup device of the type described in Example 1 with an underlying porous Aquaplast sheet (WFR/Aquaplast Corp.,  
 10 Wyckoff, NJ 07481) was placed on the Prolene mesh/wound surface and the space closed with a tent of Ioban. 34.5 kPa (5 psi) of continuous negative pressure was applied. The device was changed three times per week.

After 6 days, granulation tissue had grown through the Prolene mesh, totally covering the mesh. The patient was taken to the operating room where the surrounding tissue was undermined and grafted onto the wound to partially close the defect. Split thickness skin grafts were used to cover the remainder of the defect, and were placed on the bed of  
 15 granulation tissue. The wound accepted 80 % of the grafts, and the remaining areas closed with dressing changes alone.

## EXAMPLE 7

Treatment of Ankle Osteomyelitic Ulcer With Negative Pressure

Mr. R.F. is a 39-year-old white male who had severe trauma to his left lower extremity secondary to a motor vehicle accident 10 years ago. He had contracted chronic osteomyelitis and an open ulcer with exposed bone of his left lateral ankle (lateral malleolar ulcer). Necrotic soft tissue and bone were surgically removed from the ankle. The patient was  
 25 placed on a 2-1/2 week course of antibiotics. The day after surgery, a reduced pressure device of the type described in Example 1 was placed over the wound, and a negative pressure of 34.5 kPa (5 psi) was applied. The device was changed on a three times per week schedule. After 14 days of treatment, the wound was smaller and filled with granulation tissue. A split thickness skin graft was placed over the center of the defect and healed primarily.

## EXAMPLE 8

Treatment of Burn With Negative Pressure

Patient B. is admitted with second and third degree burns over the face and upper extremities, including both  
 35 hands, as a result of a house fire. A large mitten-shaped reduced pressure device of the type described in Example 4 is placed over the patient's right hand, with open cell foam inserts placed between the fingers to apply reduced pressure to the interdigit spaces. A vacuum of 20.7 kPa (3 psi) is applied cyclically in a pattern of 5 minutes on, 5 minutes off. The device is changed on a three times per week schedule. Treatment is continued until the necrotic tissue sloughs off or is excised, followed by split thickness skin graft placement.

40 The foregoing examples are illustrative of the present invention, and are not to be construed as limiting thereof. The invention is defined by the following claims, with equivalents of the claims to be included therein.

## Claims

- 45 1. An apparatus for facilitating the healing of a wound, comprising vacuum means (11,23) for creating a negative pressure on the area of the skin including and surrounding the wound and sealing means (12,20) operatively associated with said vacuum means for maintaining said negative pressure on said wound by contacting the skin surrounding said wound, characterised in that said negative pressure is between about 10.1 and 100.3 kPa (0.1 and 0.99 atmospheres) and in that said apparatus comprises screen means (10,24) for positioning at the wound within the  
 50 sealing means for preventing overgrowth of tissue at the wound.
2. An apparatus according to claim 1, in which said screen means (10,24) comprises an open-cell polymer foam.
3. An apparatus according to claim 1, in which said screen means (10, 24) comprises a flat, porous, semi-rigid member.  
 55
4. An apparatus according to claim 1, 2, or 3, in which said sealing means (12,20) includes a flexible sealing rim in contact with said skin surrounding said wound.

5. An apparatus according to claim 1 or 2 in which said sealing means (12) includes a flexible polymer sheet overlying said screen means, said polymer sheet having adhesive on at least a surface facing the wound to attach and seal said polymer sheet to said surrounding skin.
6. An apparatus according to claim 1 or 3, in which said sealing means (20) includes a semi-rigid cup (21) configured to protect said wound from external contact.
7. An apparatus according to claim 6, in which said sealing means (20) includes a sealing cuff (22) in contact with said skin surrounding the wound.
8. An apparatus according to claim 7, in which said sealing cuff (22) is inflatable.
9. An apparatus according in to claim 1, which includes an open-cell foam section (10) configured to overlie the wound, and in which said sealing means (12) includes a fluid-impermeable flexible cover overlying said foam section, said cover adapted to form a seal with skin surrounding the wound for maintaining negative pressure beneath said cover, and in which said vacuum means (11) includes a single tubular member having a first end inserted beneath at least a portion of the foam section (10) and having a second end extending from said cover to a location external to said cover for supplying negative pressure beneath the cover.
10. An apparatus according to claim 9, in which said first end of the tubular member (11) is inserted within the foam section (10).
11. An apparatus according to claim 1, in which said sealing means (20) includes:
  - a) a semi-rigid, fluid-impermeable cup (21) for positioning over the wound and for maintaining a negative pressure upon said wound, said cup (21) having only a single external fluid communication port; and
  - b) seal means for sealing said cup about the wound, said seal means including a cuff (22) for inflating and conforming to the surrounding skin to seal said cup (21) in place by said negative pressure; and wherein said vacuum means (23) is connected with said fluid communication port of said cup (21) for supplying said negative pressure.
12. An apparatus according to claim 11, which comprises screen means for positioning beneath the cup at the wound for preventing overgrowth of the wound.
13. An apparatus according to any one preceding claim, in which said vacuum means (11,23) includes pump means capable of providing at least 689.5 Pa (0.1 psi) suction.
14. An apparatus according to any one of claims 1 to 12, in which said vacuum means (11,23) includes a pump means capable of providing at least 20.7 kPa (3 psi) suction.
15. An apparatus according to any one of claims 1 to 12, in which said vacuum means (11,23) includes a pump means capable of providing at least 96.5 kPa (14 psi) suction.
16. An apparatus according to any one preceding claim, in which said vacuum means (11,23) operates continuously.
17. An apparatus according to any one of claims 1 to 15, in which said vacuum means (11,23) operates cyclically to provide periods of application and non-application of suction.
18. An apparatus according to claim 1 wherein the screen means (10) includes an open cell polymer foam section configured to overlie the wound; and wherein the vacuum means (11) includes a flexible tube having an inlet end and an outlet end, said inlet end being inserted into said open cell polymer foam section (10).
19. An apparatus according to claim 18, which is in an aseptic package.
20. The apparatus according to claim 17, wherein said vacuum means (11,23) operates cyclically to provide periods of application and non-application of suction with the ratio of duration of application period to non-application period between about 1:10 and 10:1.

21. An apparatus according to any one preceding claim wherein said vacuum means (11,23) supplies a negative pressure between about 30,4 and 100,3 kPa (0.3 and 0.99 atmospheres) to the wound.
22. An apparatus according to any one preceding claim wherein said vacuum means (11,23) supplies a negative pressure between about 50,7 and 100,3 kPa (0.5 and 0.99 atmospheres) to the wound.
23. An apparatus according to any one preceding claim wherein said vacuum means (11,23) supplies a negative pressure between about 50,7 and 81,1 kPa (0.5 and 0.8 atmospheres) to the wound.

#### 10 Patentansprüche

1. Vorrichtung zur Förderung der Wundheilung, die ein Vakuummittel (11, 23) zur Erzeugung eines Unterdrucks auf dem die Wunde beinhaltenden und diese umgebenden Hautbereich, sowie ein Verschlüßmittel (12, 20), das zur Aufrechterhaltung des besagten Unterdrucks auf jener Wunde durch Kontaktierung der die besagte Wunde umgebenden Haut in Wirkverbindung mit diesem Vakuummittel steht, umfaßt, dadurch gekennzeichnet, daß besagter Unterdruck zwischen ca. 0,1 und 0,99 atm beträgt und daß besagte Vorrichtung ein Schutzmittel (10, 24) zur Positionierung an der Wunde innerhalb des Verschlüßmittels zur Verhinderung eines übermäßigen Gewebswachstums an der Wunde umfaßt.
2. Vorrichtung nach Anspruch 1, bei der besagtes Schutzmittel (10, 24) einen offenzelligem Polymer-Schaumstoff umfaßt.
3. Vorrichtung nach Anspruch 1, bei der besagtes Schutzmittel (10, 24) aus einem flachen, porösen, halbstarren Glied besteht.
4. Vorrichtung nach Anspruch 1, 2 oder 3, bei der besagtes Verschlüßmittel (12, 20) einen flexiblen Dichtrand umfaßt, der mit der die besagte Wunde umgebenden Haut in Berührung steht.
5. Vorrichtung nach Anspruch 1 oder 2, bei der besagtes Verschlüßmittel (12) eine flexible Polymerfolie aufweist, die über jenem Schutzmittel liegt, wobei besagte Polymerfolie auf mindestens einer der Wunde zugewandten Oberfläche mit Klebstoff versehen ist, um jene Polymerfolie an der umgebenden Haut zu befestigen und abzudichten.
6. Vorrichtung nach Anspruch 1 oder 3, bei der das Verschlüßmittel (20) eine halbstarre Schale (21) aufweist, so ausgeführt ist, daß sie die die Wunde vor äußeren Einflüssen schützt.
7. Vorrichtung nach Anspruch 6, bei der besagtes Verschlüßmittel (20) eine Dichtmanschette (22) enthält, die mit der die Wunde umgebenden Haut in Berührung steht.
8. Vorrichtung nach Anspruch 7, bei der besagte Dichtmanschette (22) aufblasbar ist.
9. Vorrichtung nach Anspruch 1, die einen die Wunde überdeckenden Abschnitt (10) aus offenzelligem Schaumstoff umfaßt und bei der besagtes Verschlüßmittel (12) eine flüssigkeitsundurchlässige flexible Abdeckung über besagtem Schaumstoffabschnitt enthält, wobei besagte Abdeckung zur Bildung einer Dichtung mit der die Wunde umgebenden Haut ausgelegt ist, um einen Unterdruck unter dieser Abdeckung aufrechtzuerhalten, und bei der besagtes Vakuummittel (11) ein einzelnes röhrenförmiges Glied einschließt, dessen eines Ende unter mindestens einem Teil des Schaumstoffabschnitts (10) eingeschoben ist und dessen anderes Ende sich von jener Abdeckung zu einer Stelle außerhalb der Abdeckung erstreckt, um unterhalb der Abdeckung Unterdruck zu liefern.
10. Vorrichtung nach Anspruch 9, bei der das eine Ende des röhrenförmigen Glieds (11) in den Schaumstoffabschnitt (10) eingeschoben ist.
11. Vorrichtung nach Anspruch 1, bei der besagtes Verschlüßmittel (20) folgendes umfaßt:
  - a) eine halbstarre, flüssigkeitsundurchlässige Schale (21) zur Positionierung über der Wunde und zur Aufrechterhaltung eines Unterdrucks auf jener Wunde, wobei besagte Schale (21) nur eine einzige externe Flüssigkeitsöffnung aufweist; und
  - b) ein Verschlüßmittel zur Abdichtung besagter Schale um die Wunde herum, wobei besagtes Verschlüßmittel ein aufblasbare Manschette (22) beinhaltet, die sich der umgebenden Haut anschmiegt, um besagte Schale

(21) durch besagten Unterdruck an Ort und Stelle abdichten;  
und wobei besagtes Vakuummittel (23) mit besagter Flüssigkeitsöffnung besagter Schale (21) zur Lieferung des Unterdrucks verbunden ist.

- 5 12. Vorrichtung nach Anspruch 11, die ein Schutzmittel zur Positionierung unter der Schale an der Wunde zur Verhinderung eines übermäßigen Gewebswachstums der Wunde enthält.
13. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der besagtes Vakuummittel (11, 23) eine Pumpe umfaßt, die einen Saugdruck von mindestens 689,5 Pa aufbringen kann.
- 10 14. Vorrichtung nach einem der Ansprüche 1 bis 12, bei der besagtes Vakuummittel (11, 23) eine Pumpe umfaßt, die einen Saugdruck von mindestens 20,7 kPa aufbringen kann.
- 15 15. Vorrichtung nach einem der Ansprüche 1 bis 12, bei der besagtes Vakuummittel (11, 23) eine Pumpe umfaßt, die einen Saugdruck von mindestens 96,5 kPa aufbringen kann.
16. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der besagtes Vakuummittel (11, 23) kontinuierlich arbeitet.
- 20 17. Vorrichtung nach einem der Ansprüche 1 bis 15, bei der besagtes Vakuummittel (11, 23) zyklisch arbeitet, wobei sich Zyklen, in denen Saugdruck aufgebracht wird, mit Zyklen, in denen kein Saugdruck aufgebracht wird, abwechseln.
- 25 18. Vorrichtung nach Anspruch 1, bei der das Schutzmittel (10) einen Abschnitt aus offenzelligem Schaumstoff enthält, der über die Wunde gelegt wird; und worin das Vakuummittel (11) einen flexiblen Schlauch beinhaltet, der ein Einlaßende und ein Auslaßende aufweist, wobei besagtes Einlaßende in besagten Abschnitts (10) aus offenzelligem Polymer-Schaumstoff eingeführt wird.
19. Vorrichtung nach Anspruch 18, die sich in einer aseptischen Verpackung befindet.
- 30 20. Vorrichtung nach Anspruch 17, bei der bei jenem Vakuummittel (11, 23), das zyklisch Saugdruck aufbringt, das Verhältnis der Dauer der Aufbringung zur Dauer der Nicht-Aufbringung ca. 1:10 bis 10:1 beträgt.
- 35 21. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der besagtes Vakuummittel (11, 23) einen Unterdruck zwischen ca. 0,3 und 0,99 atm zur Wunde liefert.
22. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der besagtes Vakuummittel (11, 23) einen Unterdruck zwischen ca. 0,5 und 0,99 atm zur Wunde liefert.
- 40 23. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der besagtes Vakuummittel (11, 23) einen Unterdruck zwischen ca. 0,5 und 0,8 atm zur Wunde liefert.

#### Revendications

- 45 1. Appareil pour faciliter la cicatrisation d'une plaie, comprenant un moyen de vide (11, 23) pour créer une pression négative sur la zone de la peau comportant et entourant la plaie, et un moyen de scellage (12, 20) associé en fonctionnement audit moyen de vide pour maintenir ladite pression négative sur ladite plaie en venant au contact de la peau entourant ladite plaie, caractérisé en ce que ladite pression négative est entre environ 0,1 et 0,99 atmosphère et en ce que ledit appareil comprend un moyen de filtre (10, 24) destiné à être placé au niveau de la plaie à l'intérieur du moyen de scellage pour empêcher une excroissance de tissu au niveau de la plaie.
- 50 2. Appareil selon la revendication 1, dans lequel ledit moyen de filtre (10, 24) comprend une mousse polymère à alvéoles ouvertes.
- 55 3. Appareil selon la revendication 1, dans lequel ledit moyen de filtre (10, 24) comprend un organe semi-rigide, poreux, plat.
4. Appareil selon la revendication 1, 2 ou 3, dans lequel ledit moyen de scellage (12, 20) comporte une levre de scel-

lage flexible en contact avec ladite peau entourant ladite plaie.

5. Appareil selon la revendication 1 ou 2, dans lequel ledit moyen de scellage (12) comporte une feuille polymère flexible recouvrant ledit moyen de filtre, ladite feuille polymère ayant de l'adhésif au moins sur une surface faisant face à la plaie pour attacher et sceller ladite feuille polymère à ladite peau environnante.
6. Appareil selon la revendication 1 ou 3, dans lequel ledit moyen de scellage (20) comporte une coupelle semi-rigide (21) configurée de manière à protéger ladite plaie d'un contact extérieur.
7. Appareil selon la revendication 6, dans lequel ledit moyen de scellage (20) comporte une manchette de scellage (22) en contact avec ladite peau entourant la plaie.
8. Appareil selon la revendication 7, dans lequel ladite manchette de scellage (22) est gonflable.
9. Appareil selon la revendication 1, qui comporte une section de mousse (10) à alvéoles ouvertes, configurée de manière à recouvrir la plaie, et dans lequel ledit moyen de scellage (12) comporte un recouvrement flexible imperméable aux fluides recouvrant ladite section de mousse, ledit recouvrement étant adapté pour former un joint avec la peau entourant la plaie pour maintenir une pression négative sous ledit recouvrement, et dans lequel ledit moyen de vide (11) comporte un organe tubulaire unique ayant une première extrémité insérée sous au moins une portion de la section de mousse (10) et ayant une deuxième extrémité s'étendant depuis ledit recouvrement jusqu'à un emplacement en dehors dudit recouvrement pour fournir de la pression négative sous le recouvrement.
10. Appareil selon la revendication 9, dans lequel ladite première extrémité de l'organe tubulaire (11) est insérée à l'intérieur de la section de mousse (10).
11. Appareil selon la revendication 1, dans lequel ledit moyen de scellage (20) comporte:
  - a) une coupelle semi-rigide (21) imperméable aux fluides, destinée à être positionnée par-dessus la plaie et à maintenir une pression négative sur ladite plaie, ladite coupelle (21) ayant seulement un port unique de communication externe de fluide; et
  - b) un moyen de scellage pour sceller ladite coupelle autour de la plaie, ledit moyen de scellage comportant une manchette (22) destinée à être gonflée et à épouser la forme de la peau environnante de manière à sceller ladite coupelle (21) en place sous l'effet de ladite pression négative;  
et dans lequel ledit moyen de vide (23) est connecté audit port de communication de fluide de ladite coupelle (21) pour fournir ladite pression négative.
12. Appareil selon la revendication 11, qui comprend un moyen de filtre destiné à être positionné sous la coupelle au niveau de la plaie pour empêcher l'excroissance de la plaie.
13. Appareil selon l'une quelconque des revendications précédentes, dans lequel ledit moyen de vide (11, 23) comporte un moyen de pompe capable de fournir au moins une aspiration de 689,5 Pa.
14. Appareil selon l'une quelconque des revendications 1 à 12, dans lequel ledit moyen de vide (11, 23) comporte un moyen de pompe capable de fournir au moins une aspiration de 20,7 kPa.
15. Appareil selon l'une quelconque des revendications 1 à 12, dans lequel ledit moyen de vide (11, 23) comporte un moyen de pompe capable de fournir au moins une aspiration de 96,5 kPa.
16. Appareil selon l'une quelconque des revendications précédentes, dans lequel ledit moyen de vide (11, 23) fonctionne en continu.
17. Appareil selon l'une quelconque des revendications 1 à 15, dans lequel ledit moyen de vide (11, 23) fonctionne cycliquement pour fournir des périodes d'application et des périodes de non application d'aspiration.
18. Appareil selon la revendication 1, dans lequel le moyen de filtre (10) comporte une section de mousse polymère à alvéoles ouvertes configurée de manière à recouvrir la plaie; et dans lequel le moyen de vide (11) comporte un tube flexible ayant une extrémité d'entrée et une extrémité de sortie, ladite extrémité d'entrée étant insérée dans ladite section de mousse polymère (10) à alvéoles ouvertes.

19. Appareil selon la revendication 18, qui est sous emballage aseptique.

20. Appareil selon la revendication 17, dans lequel ledit moyen de vide (11, 23) fonctionne cycliquement pour fournir des périodes d'application et des périodes de non application d'aspiration dans un rapport de durée de période d'application sur période de non application d'environ 1:10 à 10:1.

21. Appareil selon l'une quelconque des revendications précédentes, dans lequel ledit moyen de vide (11, 23) fournit à la plaie une pression négative entre environ 0,3 et 0,99 atmosphère.

22. Appareil selon l'une quelconque des revendications précédentes, dans lequel ledit moyen de vide (11, 23) fournit à la plaie une pression négative entre environ 0,5 et 0,99 atmosphère.

23. Appareil selon l'une quelconque des revendications précédentes, dans lequel ledit moyen de vide (11, 23) fournit à la plaie une pression négative entre environ 0,5 et 0,8 atmosphère.

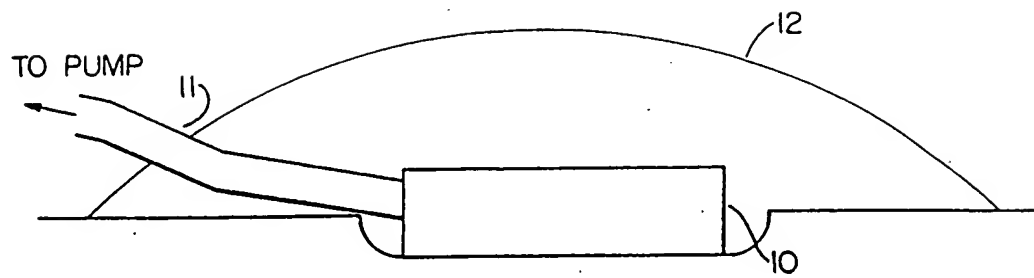


FIG. 1.

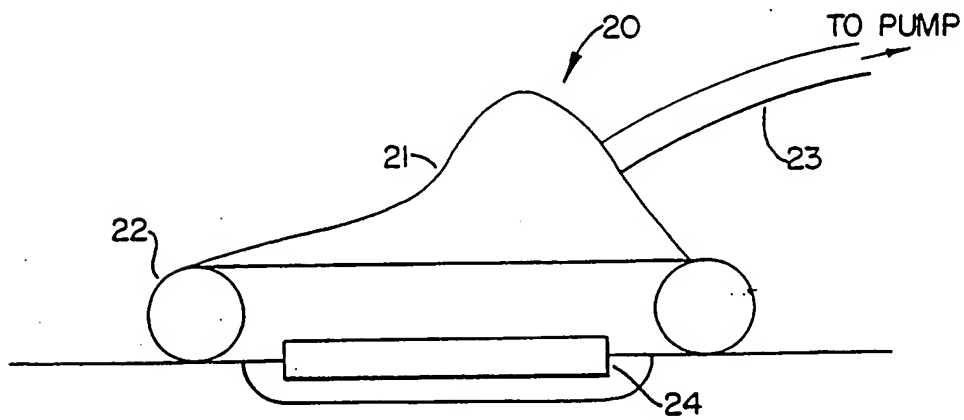


FIG. 2.